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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,430	09/21/2000	Delphine Gabrielle Josette Rea	4205.1US	6289

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09/19/2002

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 09/19/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/666,430

Applicant(s)

Rea et al.

Examiner

G.R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 24, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 9-15, and 28-36 is/are pending in the application.
- 4a) Of the above, claim(s) 30-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, 9-15, 28, and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I, Claims 1, 5-7, 9-15, and 28-29, in Paper No. 10, filed 3/22/02, without traverse, is acknowledged. Applicant's additional election of the species CD8-CD40L fusion protein, with traverse, is acknowledged. Upon further consideration, the species requirement has been withdrawn.

Claims 4, 7-8, and 17-19 have been canceled.
Claims 1, 5-6, 9-15, and 28-29 are being acted upon.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 5-6, 9-15, and 28-29 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

the *in vitro* induction of non-responsiveness of MHC-matched clonal T cells to a defined antigen when dexamethasone-treated dendritic cells have been loaded with the same defined antigen, does not reasonably provide enablement for,

in vivo or *in vitro* induction of non-responsiveness of polyclonal T cells to any undefined antigen or the *in vivo* induction of non-responsiveness when an "unwanted T-cell response" is ongoing, for the reasons of record as set forth in Paper No. 6, mailed 6/29/01.

Applicant's arguments, filed 6/24/02, have been fully considered but they are not persuasive. Applicant argues that, rather than targeting the activated T cells disclosed in the prior art, "the present invention discloses targeting dendritic cell activation by transforming an alternative activation pathway," and "Thus, the present invention shows that GC, such as DEX, convert CD40 ligation on human monocyte-derived DC and is transformed into an alternate pathway." It appears then that Applicant is arguing that the invention of the instant claims functions through a previously undescribed mechanism. Said mechanism would then be considered unexpected and accordingly, unpredictable. Given the unpredictability of the invention of the instant claims, some sort of enablement, in addition to mere

assertion, would be required. The specification discloses just a single example (Example 4) in which an *in vitro* allogeneic or hsp65-specific T cell response is reduced. Said example is insufficient to support claims drawn to the production of pharmaceutical composition that assertedly functions by an unexpected and unpredictable mechanism.

4. Claims 1, 5-6, 9-15, and 28-29 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in Paper No. 6, mailed 6/29/01.

Applicant's arguments, filed 6/24/02, have been fully considered but they are not persuasive. Applicant argues, "Applicants respectfully submit that glucocorticoids are a well known class of adrenocorticotrophic hormones. (See, for example, Goodman and Gilman's The Pharmacological Basis of Therapeutics, Goodman Gilman, A et al. (Seventh Ed.) Chapter 23 Adrenocorticotrophic Hormone: Adrenocortical Steroids and their Synthetic Analogs; Inhibitors of Adrenocortical Steroid Biosynthesis, pp. 1459-1489; Remington's Pharmaceutical Sciences, Chase et al. (Sixteenth Ed.) Adrenal Hormones pp. 898-912). Glucocorticoids are discussed generally as a class with respect to physiology, biological activity, side effects, drug interactions, absorption, fate and excretion, and therapeutic uses. (Remington's, pages 898-901)." Note that Applicant argues that "Glucocorticoids are discussed generally." It is the Examiner's position that a "general" discussion or definition is insufficient to specifically describe a claimed invention. Further, see Stedman's Medical Dictionary (2002) in which glucocorticoid is defined as "any steroid-like compound capable of significantly influencing intermediary metabolism." And further wherein, "intermediary metabolism" is defined as "the sum of all metabolic reactions between uptake of foodstuffs and formation of excretory products." Clearly then "glucocorticoid" encompasses a large number of compounds capable of a large range of biological activities. Given the disclosure of just a single species of glucocorticoid (dexamethasone) one of skill in the art would conclude that the specification discloses an insufficient number of species to describe the entire genus of the claims.

5. No claim is allowed.


6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
September 10, 2002


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600